

## REMARKS

Applicant has carefully reviewed the Office Action mailed April 3, 2008 and offers the following remarks to accompany the above amendments.

### Status of the Claims

Claims 1, 5, 7, 9, 11-15, 17-20, 22, 24, and 26-45 are pending in the present application.

Claims 2-4, 6, 8, 10, 16, 21, 23, and 25 were previously cancelled.

Claims 26-45 were previously withdrawn.

Claims 1 is amended to address the Examiner's comments on page 4 of the Office Action mailed on April 3, 2008 as will be discussed in more detail when addressing Vaschillo below.

### The "Claimed Invention"

Applicant previously provided a brief explanation of the claimed invention in the response accompanying the Request for Continued Examination filed February 19, 2008 (see also, response to final Office Action mailed on November 29, 2007). In lieu of repeating these explanations, Applicant incorporates them herein by reference.

### Rejection under 35 U.S.C. § 102(b) – Vaschillo et al.

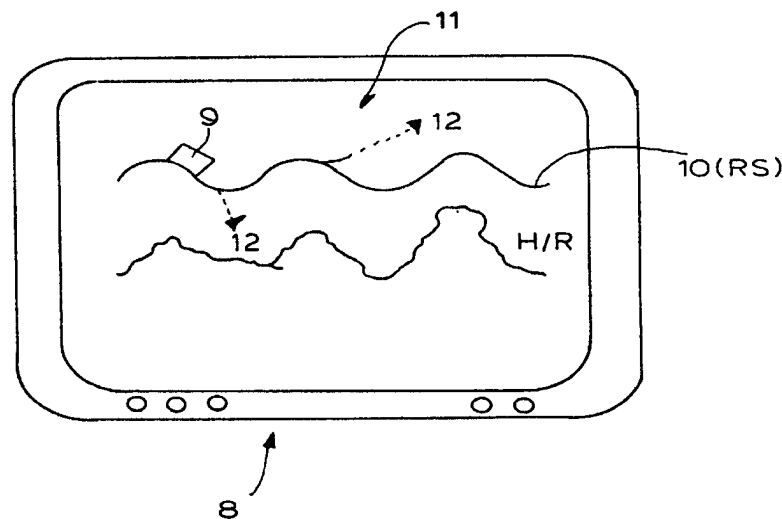
The Patent Office continues to maintain a rejection of claims 1, 5, 7, 9, 11-15, 17-20, 22, and 24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter "Vaschillo"). Applicant respectfully traverses in light of the amendment to claim 1. For the Patent Office to prove anticipation, each and every element of the claims must be present in the reference. Furthermore, the elements of the reference must be arranged as claimed. MPEP § 2131.

Claim 1 is amended in response to the Examiner's comments on page 4 of the Office Action mailed on April 3, 2008. This amendment is made to clarify that the nature of the instruction provided to the human patient is different than the cited art, and thus is not anticipated or obvious. Claim 1 is amended to provide that the human subject is instructed on the moment to breathe such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate. Greater consistency results in a more coherent heart rate variability (HRV) (See response to final Office Action, page 9).

Greater consistency in a patient's natural heart rate can be achieved by a patient aligning their breathing cycle with their natural heart rate cycle. *Id.* at 10 The claimed invention provides this breathing instruction to the patient such that the patient aligns their breathing cycle to their natural heart rate cycle. The patient breathes in response to the instruction to align their breathing cycle with their natural heart rate cycle. This is in response to the inventor's recognition that a patient's breathing cycle influences a patient's heart beat rate cycle. *Id.*

Vaschillo does not instruct a human patient to breathe based on their natural heart rate cycle, as provided in the claimed invention. Instead, as illustrated in Figure 2 below, Vaschillo instructs the patient to breathe in accordance with a predetermined reference signal (RS) (Vaschillo, col. 6, ll. 52-55). The reference signal (RS) is not a biofeedback of the patient's heartbeat rate, but is instead a predetermined signal at one possible breathing cycle frequency (Vaschillo, col. 6, ll. 52-55). The patient is instructed to breathe according to the reference signal (RS) on a display (8). The patient is informed whether their breathing is in accordance with the reference signal (RS) (H/R signal in Figure 2). Vaschillo then records the patient's heartbeat cycle that results from the patient breathing at the reference signal (RS) frequency.

**FIG. 2**



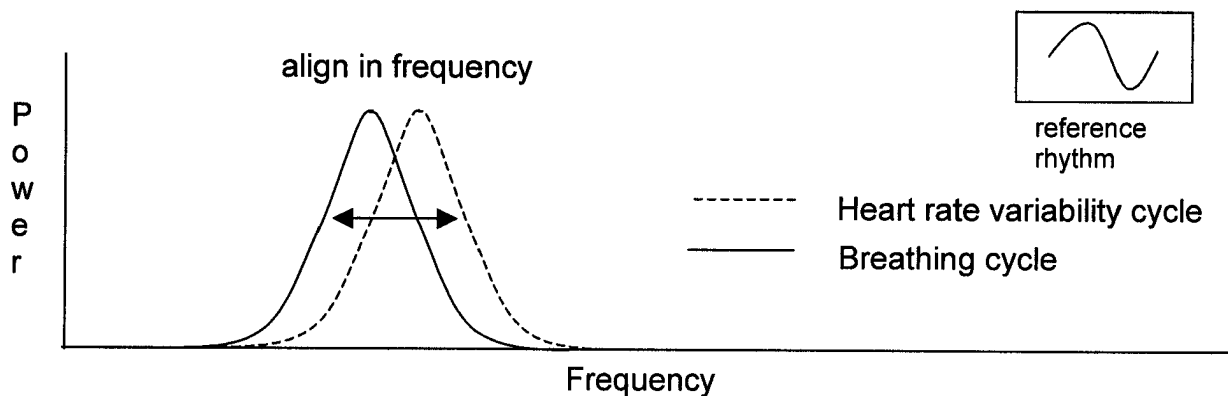
Vaschillo repeats these steps over a series of varied reference signal (RS) frequencies in a sweeping fashion. This data is then analyzed to determine at which reference signal (RS) frequency the patient's breathing aligns (i.e. resonates) with their heartbeat cycle. Phase shift differences between the reference signal (RS) frequency and the patient's heart rate are analyzed

in the frequency domain to determine resonance, or lack thereof. Zero phase shift represents resonance. Figures 4A-4B of Vaschillo illustrate this data recordation and analysis.

Thus, Vaschillo instructs the patient to breathe based on a variety of reference signals (RS) and not any biofeedback signal. Vaschillo is just a monitoring system that does nothing to instruct the patient on how to align their breathing with their natural heart rate. Vaschillo's goal is to simply monitor and determine the current state of the patient's heart rate cycle (i.e. the resonance frequency). No instructions are provided to the patient to breathe according to their own heart beat rate or any other biofeedback.

On the contrary, the claimed invention is not a tool to quantify resonance based on theoretical breathing reference signals like in Vaschillo. The claimed invention instructs the patient on the actual breathing cycle such that the patient breathes to align their breathing cycle to their natural heart rate cycle to attempt to achieve coherence. The claimed invention provides an instruction signal based on actual biofeedback from the patient's heartbeat cycle. Vaschillo does not. Vaschillo is designed to analyze the current state of the patient's heartbeat. The claimed invention is designed to instruct and have the patient breathe to achieve coherence regardless of the current state of the patient's heartbeat. Vaschillo analyzes, whereas the claimed invention instructs and achieves.

A further, but related distinction lies in the fact that Vaschillo performs its analysis in the frequency domain. The claimed invention is not analyzing data in the frequency domain, because the claimed invention is not analyzing at what breathing frequency the patient's heartbeat is resonant. The claimed invention is instructing the patient on how to breathe to reach coherence regardless of the current state of the patient's heart. This distinction is illustrated in the drawing below. This drawing represents Vaschillo's operation, wherein a phase difference is measured between the patient's heartbeat and their breathing cycle to determine resonance, or lack thereof.



Goal: Identify exact frequency of resonance

Frequency at which alignment occurs is exact frequency of resonance

Applicant respectfully submits that Vaschillo does not anticipate claim 1. Claims 5, 7, 9, 11-15, 17-20, 22, and 24 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, 22, and 24 should be withdrawn for at least the same reasons.

Rejection under 35 U.S.C. § 103(a) – Stabler et al.

Claims 1, 5, 7, 9, 11-15, 17-20, and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,836,681 B2 to Stabler et al. (hereinafter “Stabler”).

Applicant respectfully traverses. For the Patent Office to establish *prima facie* obviousness, the Patent Office must show where each and every claim element can be found in the reference. MPEP § 2143.03.

Applicant has amended claim 1 to provide that the human subject is instructed on the moment to breathe such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate, as previously discussed. Specifically, the human subject is instructed on the moment to inhale and exhale based on the biofeedback signal indicating the transitions in the human subject’s heart beat cycle.

Stabler does not instruct a human to have them breathe at a target rate based on the patient’s heart rate cycle (Stabler, col. 2, ll. 35-38). Instead, Stabler simply displays a graph of heart rate variability and amplitude of breathing results to the patient. The graph only indicates to the patient that they are in “the zone,” which Stabler makes clear is relative to the amplitude of the HRV cycle.. Stabler does not teach or suggest that these results provide instructions to the

patent to breathe such that the patient aligns their breathing cycle with their heart rate cycle. Nor does the patient in Stabler breathe according to the results provided on the display. The patient is simply given the results to indicate if the patient is in the "zone" without any real understanding of the relationship of inhalations and exhalations to transitions in the natural heart beat rate cycle (col. 4, ll. 1-17). Stabler simply requires the patient to continue breathing in a controlled fashion until the patient gets it right and reaches the "zone." A breakthrough in the Applicant's invention is the recognition of inhalation and exhalation in breathing cycle to coherence and instructing the patient specifically at the transition times as to when to inhale and exhale. Thus, Stabler does not render the claimed invention obvious, and thus this rejection must be withdrawn.

Claims 5, 7, 9, 11-15, 17-20, and 22 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, and 22 should be withdrawn for at least the same reasons as claim 1. Applicant respectfully submits that claims 1, 5, 7, 9, 11-15, 17-20, and 22 are in condition for allowance and notice of the same is requested at the earliest possible date.

#### Conclusion

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant's representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

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